

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: :  
: Angelo Ariotto et al. : Group Art Unit: 1616  
: :  
Serial No.: 10/566,030 : Examiner: Fisher, Abigail L  
: :  
Filed: January 17, 2006 :  
:

For: A CLEANSING COMPOSITION BASED ON OILY SUBSTANCES

**DECLARATION**

I, Elisabetta Merlo, hereby declare the following:

1. My scientific curriculum is attached as annex 3 to the present declaration; I am presently acting as an employee of Zschimmer & Schwarz Italiana S.r.l., and I am a co-inventor of the above-identified patent application.
2. The invention provides a cleansing composition based on oily substances, useful for cleansing skin and/or hair and having excellent dermatological properties. The composition of the invention comprises one or more oily substances at a total concentration of 30% to 70% by weight and a surfactant selected from N-acylates of amino acids, peptides and proteins of Formula (I) or mixtures thereof, at a total concentration of 10% to 40% by weight. The composition of the invention has a water content not greater than 10% by weight. The composition of the invention is in a liquid form.
3. Prior to the invention of the above-identified application, N-acylates of amino acids, peptides and proteins of Formula (I) were known in the prior art as surfactants suitable for use in cosmetic formulations such as, *inter alia*, soaps.
4. The reference International Journal of Toxicology, 20(Suppl.1):1-14, 2001, cited by the Examiner in the Office Action dated January 27, 2010, discloses the use of acyl sarcosines and sarcosinates as surfactant-cleansing agents in cosmetic formulations. This reference specifically discloses the use of Sodium Lauroyl Sarcosinate at concentrations of 2.78% to 6.86% in two liquid soaps and at concentrations of 12.5% to 12.9% in a bar soap.

5. Gerber et al. in US Patent No. 5653988, cited by the Examiner in the Office Action dated January 27, 2010, disclose a shower oil containing not more than 55% by weight of one or more surfactants selected from the group of fatty alcohol ethoxylates, fatty alcohol sulphates, amides of fatty alcohol sulphates, fatty alcohol ether sulphates, amides of fatty alcohol ether sulphates, fatty acid monoethanolamides, fatty acid diethanolamides, and not less than 45% by weight of one or more oil components selected from the group of oils with a high content of triglycerides of saturated and/or unsaturated, branched and/or unbranched fatty acids, or exclusively such triglycerides. The shower oil disclosed in Gerber et al. is essentially anhydrous. It may contain optional components such as further surfactants, as well as further cosmetic or pharmaceutical auxiliaries, additives, active substances.

According to column 3, lines 32-36 of Gerber et al., it is preferred to employ mixtures of MIPA laureth sulphate, laureth-4 and Cocamide-DEA, such as e.g. the surfactant mixture marketed by Zschimmer & Schwarz under the trade name ZETESOL®100.

6. Stork et al. in US Patent No. 6620773, cited by the Examiner in the Office Action dated January 27, 2010, disclose a foaming oil preparation extremely well tolerated by the skin, mucosa and eyes, which comprises at least a surfactant mixture and an oil component. The surfactant mixture comprises at least an anionic or zwitterionic surfactant, a nonionic surfactant and an alkyl phosphate compound. Specific examples of such surfactant mixtures are provided in the examples.
7. However, neither Gerber et al. nor Stork et al. mention as suitable surfactants the N-acylates of amino acids, proteins and peptides of Formula (I) identified in Claim 1 of the present patent application.
8. Attached herewith, as annexes 1 and 2, are two experimental reports concerning eye irritation tests performed to evaluate the tolerability of a cosmetic formulation falling within the definition of Claim 1 of the present patent application, that is to say a formulation of Oleoyl Sarcosine in bath oils.

The tolerability is expressed in terms of Inhibiting Concentration 50 (IC<sub>50</sub>), which is the concentration of the test formulation which is capable of inducing a 50% decrease in the cell growth/survival. The IC<sub>50</sub> value is commonly used as an indication of the potential irritating effect of a test compound or formulation, an consequently of its tolerability (the lower the IC<sub>50</sub>, the lower the tolerability).

As a comparison, the effects of two reference preparations, one containing the same surfactant (i.e. Oleoyl Sarcosine) but formulated in water, and the other based on bath

oils but containing a conventional surfactant mixture marketed as ZETESOL 100, were also evaluated under the same conditions.

9. A detailed description of the different formulations tested in annexes 1 and 2 is provided herein below.
- (i) The formulation designated as **Sample A in Annex 1** (Oleoyl Sarcosine in water) consists of the following mixture:
- 55% Water
  - 31% Oleoyl Sarcosine
  - 6.4% AMP (Amino methyl propanole)
  - 7.6% Laureth-4 (ethoxylated alcohol)
- The product is a turbid viscous gel giving rise to a murky solution at the concentration used in the test.
- (ii) The formulation designated as **Sample B in Annex 2** (Oleoyl Sarcosine in bath oil) consists of the following mixture:
- 44% Glicine Soja
  - 11% Ricinus Communis
  - 31% Oleoyl Sarcosine
  - 6.4% AMP (Amino methyl propanole)
  - 7.6% Laureth-4 (ethoxylated alcohol)
- The water content is less than 0.1%. The product is a clear amber liquid.
- (iii) The formulation designated as **Sample A in Annex 2** (Market Leader Bath Oil) contains the following ingredients (INCI names indicated on the label):
- Glycine Soja, MIPA-Laureth Sulfate, Ricinus Communis, Laureth-4, Cocamide DEA, Poloxamer 101, Parfum, Triticum Vulgare, Citric Acid, Aqua, Panthenol, BHT, Propyl Gallate, Linalool, Butylphenyl Methylpropianol, Limonene, Citronellol, Geraniol, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, Coumarin, Alpha-Isomethyl Ionone, Eugenol, Hexyl Cinnamal.
- The surfactant is a mixture of MIPA-Laureth Sulfate, Laureth-4 and Cocamide DEA marketed as ZETESOL 100. The ZETESOL 100 total content in the product is 38-40%. The oil total content in the product is 55%. The product is a clear amber liquid
10. Annexes 1 and 2 are written both in Italian and in English. Annex 1 further contains the results obtained with a third formulation, designated as "Sample C". Such results as well as any information relating thereto have been deleted because Sample C does not relate to the case at issue.

11. The experiments in the experimental report were ordered to ABICH S.r.l., a certified service company (ISO 9001:2000) performing chemical and biological analysis, by Zschimmer & Schwarz Italiana S.r.l. The experiments were carried out by ABICH S.r.l. and the annexed reports were prepared by ABICH S.r.l.
12. I have reviewed the data illustrated in the reports and I affirm that the following conclusions can be drawn from the obtained results:
- That the cosmetic formulation which is by far better tolerated is the formulation of Oleoyl Sarcosine in oils (Sample B in Annex 1), which is the formulation according to the present invention. The  $IC_{50}$  of Sample B in Annex 1 is 0.72 mg/ml, which is more than one order of magnitude higher than the  $IC_{50}$  of the formulation of Oleoyl Sarcosine in water (Sample A in Annex 2,  $IC_{50} = 0.03$  mg/ml).
- Furthermore, the  $IC_{50}$  value of the formulation according to the present invention is exactly one order of magnitude higher than the  $IC_{50}$  of the Market Leader Bath Oil formulation (Sample A in Annex 1,  $IC_{50} = 0.072$  mg/ml).
- It is worth noticing that the  $IC_{50}$  values of the formulation of Oleoyl Sarcosine in water and of the Market Leader Bath Oil formulation are of the same order of magnitude as the  $IC_{50}$  of the irritant positive control.
- The significant reduction in the eye irritation potential observed with the formulation according to the present invention is therefore unexpected in the light of the high irritation potential of both reference formulations.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these were made with the knowledge that false statements made willfully are punishable by fine, imprisonment, or both a fine and imprisonment under Section 1001 of Title 18 of the United States; and further that false statements made willfully may jeopardize the validity of any patent issuing on a patent application in which the false statements were made.

Annexes 1 and 2: Experimental Reports  
Annex 3: Scientific curriculum

Date:

07/06/2010

  
Elisabetta Merlo